Hello. My name is Kelli Oster from the Grants Management Office of the National Institute of Nursing Research, and my presentation today is going to cover the funding and award process from a grants management perspective.

Discussion Topics

- Just in Time (JIT)
- Interpreting the Notice of Award
- Progress Reports
- Closeout Requirements

In this presentation, I will be discussing:

•Just in Time – What it is and how to respond.

•Interpreting the Notice of Award

•Annual Progress Reports, if they are required and

•Closeout Requirement to complete the administrative process for receiving a Federal Grant through the NIH.

Just in Time (JIT)

Automatic JIT requests are sent from CSR

- Other support for all Senior/Key personnel
- IRB approval
- Human subjects education certification
- IACUC approval

So you have now submitted your application, received your summary statement and were given a great score! Congratulations… Now it's time for the Just in Time process to begin.

Automatic JIT requests are sent from the Center for Scientific Review (CSR) based on certain score criteria. Receiving a JIT request does not mean that your application is guaranteed funding. But it does mean that the NINR may be considering your application for Support.

The standard elements for a Just In Time Request include other support for key personnel; IRB approval if human subjects will be involved; human subjects education certification; and IACUC approval if your project involves vertebrate animals. Other project-specific information may also be requested directly by NINR if necessary.

Other Support

- Ensures sufficient levels of effort committed to the project, without scientific, budgetary or commitment overlap
- Used only for key personnel, as identified by the grantee
- Reflect support in person months (12 PM effort = 100% effort)
- No effort totals more than 12 person months including effort requested for subject grant

Taking a look at the First Element:Other support

is reviewed by both program directors and grants management. Grants management reviews the other support to ensure that total active effort does not exceed 12 person months (100% effort.) Program staff reviews other support to ensure there is no scientific or budgetary overlap.

This information is critical to determine that the proposed research does not duplicate currently funded research projects.

Other support should only be provided for key personnel, i.e., principal investigators, co-investigators, etc., but not consultants; and only for those individuals devoting measurable effort to a project.

The effort should be reflected in person months (12 PM effort = 100% effort), and total effort (including that requested for proposed grant) should not be greater than 12 person months.

IRB Approval

- Certification of IRB approval (must be within 12 months before the budget period start date)
- Each institution that is "engaged" in HHS supported human subjects research must obtain an Federalwide Assurance (FWA) from Office of Human Research Protection (OHRP)
- Grantee needs to provide an FWA for all performance sites where human subject research will be conducted

http://www.hhs.gov/ohrp/assurances/index.html

The second Just In time element is the Institutional Review Board approval or what is often called the (IRB) and this review and approval must be within 12 months of the budget period start date. This is required if human subjects are involved.

In addition, a Federal Wide Assurance must be provided for each institution and performance site that is "engaged" in Human Subject research. It is up to the applicant institution to determine which sites and which staff are considered engaged/

For more information on these requirements you can go to the Office of Human Research and Protections (OHRP) website that is provided on the slide.

Human Subjects Education Requirement

- Certify that each 'key personnel" has completed training in the protection of human subjects

- Submit in the form of a letter signed by the institutional official

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html

The next piece of JIT for those applications involving human subjects is the human subjects education certification, which must be submitted for all key personnel involved in the design or conduct of the study.

Again, designating who the key personnel involved in the design or conduct of a study are, is the responsibility of the applicant organization.

Grantees must submit a description of the education completed for each individual identified as "key personnel".

The certification should be submitted by the business official and the URL which discusses this requirement is noted on this slide.

IACUC Approval

- Verification of IACUC approval (must be within 3 years before the budget period start date to be valid)
- Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW)
- Ensure all consortium sites engaged in animal research have approved Assurance and valid IACUC approval
- Foreign grantees not required to provide IACUC approval, but must have Assurance

http://grants.nih.gov/grants/olaw/olaw.htm

If your application involves animals, the final JIT element that is required is the IACUC approval.

This approval must be within 3 years of the budget period start date.

The grantee institution must have an active assurance on file with the Office of Laboratory and Animal Welfare.

Similar to human subject requirements, the applicant institution is also responsible for ensuring that all consortium sites engaged in animal research also have an active assurance on file with OLAW and an IACUC approval.

Examples of Possible Additional JIT Requests

- Summary Statement: Response to human subjects or animal issues and Scientific/budgetary concerns

- Written response that resolves any concerns ("Unacceptable" designations for human subject protections, and for inclusion of women, minorities, and children)

As mentioned earlier, you may also receive an additional JIT request from NINR for information not included in the CSR request.

This tends to be a more application-specific request for additional information needed for the review of your grant.

For example, you may be asked to provide a response to human subjects or animal issues, or you may be asked to respond to any scientific or budgetary concerns identified on your Summary Statement.

JIT Submission

Can be submitted electronically or via email

- Electronically through eRA Commons (preferred method)
  - Use the Just in Time feature of the NIH Commons found in the Commons Status section
- Business official can email the requested information as a PDF document

Information on Commons: https://commons.era.nih.gov/commons/index.jsp

JIT can be submitted either electronically through the NIH commons (preferred method) or via email from an authorized business official as a PDF attachment.

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Interpreting the Notice of Award

- What is in the Notice of Award?
- What are the components of the Notice of Award?
- Acceptance of the Notice of Award
- Timeliness and avoiding delays

Moving on to the next step of the funding life cycle: Once your project is funded:

 I would like to cover how to interpreting the Notice of Award!

NEXT SLIDE

Interpreting the Notice of Award

What is in the Notice of Award?

- Identifies grantee, PI(s)
- Establishes funding level, support period
- Sets forth terms and conditions

The Notice of Award is a legally binding document which:

•Identifies the grantee and PI(s),

•Establishes the funding level and the period of support,

•Sets forth the terms and conditions of award.

It is usually sent through the eRA Commons to the business office identified for your organization.

 One important distinction to keep in mind is that the grant is made to the institution, not the PI. So even though you are conducting the research project, the grantee institution is technically the 'owner' of the grant.

Interpreting the Notice of Award

Components of the Notice of Award

NOA Section I:

Award Data & Fiscal Information

- Summary of totals for current and future years
- Provides the NIH with administrative data on the award

Section 1 of the award notice includes award data and fiscal information such as the summary of your award amounts and the fiscal year of the award.

Interpreting the Notice of Award

Components of the Notice of Award

NOA Section II:
- Grant Payment Information
- OIG Hotline Information

Section 2 of the award includes payment information and it also provides information on how to contact the Office of the Inspector General if you have a concern you wish to voice.

Interpreting the Notice of Award

Components of the Notice of Award

NOA Section III: Standard Terms & Conditions

- Grant program legislation and regulations
- Restrictions on the expenditure of funds in appropriation acts
- 45 CFR 74 or 92 as applicable
- NIH Grants Policy Statement

Section 3 of the award notice includes standard NIH terms and conditions of award.

It includes:
- Program legislation and regulations,
- Restrictions on the expenditure of funds in appropriation acts,
- Compliance with administrative requirements and the NIH Grants Policy Statement,

Interpreting the Notice of Award

Components of the Notice of Award

NOA Section III: Standard Terms & Conditions
- Carryover—automatic or requires prior approval
- Included/excluded from Streamlined Noncompeting Award Process (SNAP)
- Program Income

•Section III Continued:

It also covers if the grant is subject to:

•Carryover authority,

•Whether you grant is included or excluded from the Streamlined Noncompeting Award Process (SNAP) and

• which program income alternative applies if your project is generating income.

Interpreting the Notice of Award

Components of the Notice of Award

NOA Section IV: Specific Terms and Conditions

- Revisions
- Cooperative Agreement
- Restrictive terms
- Information items
- Staff Contact Information
- Spreadsheet Summary

Section 4 is where the grants specialist includes grant-specific terms and conditions for your individual award. This is one of the most important parts of the award notice.

I'll list some examples of terms that may be included in this section:

•Any Information regarding if or why an award was revised

•Any associated terms and conditions if this award was issued as a cooperative agreement

•Any restrictive terms, including those for funding restrictions, and

•Any informational terms not included in the standard NIH terms listed under Section III

This is also where you will see the NIH staff contact information and the spreadsheet summary of the award amount.

Non-Competing Continuation Progress Reports

- Paper progress reports are due two months prior to the anniversary date

- Research Performance Progress Reports (RPPR) are due 45 days prior to the anniversary date

- All grantees have access to a searchable list to determine which progress reports

http://era.nih.gov/userreports/pr_due.cfm

So your application was funded in the competing year and you are coming up on the end of the first budget period. If you have multiple years of support, it is now time to submit your annual progress report.

Paper submissions of progress reports are due two months prior to the anniversary date of the grant.

If your grant is included in the mechanisms that have transitioned to the Research Performance Progress Report, the RPPR is due 45 days prior to the anniversary date.

Closeout Requirements

- NIH Grants Policy Statement, October 2013
- Federal Financial Report (SF 425) must be submitted electronically through the NIH Commons
- Final Invention Statement (HHS 568)
- Final Progress Report
- All required documents should be submitted electronically within 90 days of expiration

NIH Grants Policy Statement: http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch8.htm#_Toc271264983
Electronic submission SF 425 : http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-017.html

After you have completed your project you must submit 3 closeout documents that are identified on the last NoA to administratively close out the award:

•The Federal Financial Report (SF 425),must be submitted electronically through the NIH Commons.

•The Final Invention Statement (HHS 568), and

•The Final Progress Report must also be submitted electronically and all three of these reports are due to the NIH within 90 days of the project period end date.

This concludes our presentation on the Notice of Grant Award and Managing Your Grant. If you have any questions please contact the NINR Office of Grants Management at WWW.NINR.NIH.GOV